



# MSSOURI BOARD OF PHARMACY

ANNUAL REPORT FOR THE FISCAL YEAR ENDING JUNE 30, 2003



BOB HOLDEN, GOVERNOR STATE OF MISSOURI

JOSEPH DRISKILL, DIRECTOR
DEPARTMENT OF ECONOMIC DEVELOPMENT

MARILYN TAYLOR WILLIAMS, DIRECTOR DIVISION OF PROFESSIONAL REGISTRATION





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# DEPARTMENT OF ECONOMIC DEVELOPMENT DIVISION OF PROFESSIONAL REGISTRATION BOARD OF PHARMACY MEMBERS AND STAFF

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Web Site http://www.ecodev.state.mo.us/pr/pharmacy/

#### **BOARD MEMBERS**

Martin H. Michel, R. Ph., President Elaina M. Wolzak, R. Ph., Vice President Barbara J. Dunning, R. Ph., Member Douglas R. Lang, R.Ph., Member Gary F. Sobocinski, R. Ph. Member Tim Koch, R. Ph., Member Anita K. Parran, Public Member

#### **BOARD INSPECTORS**

Thomas Glenski, R. Ph., Chief Inspector Robert "Bud" Alexander, R. Ph., Inspector Kim Kaufman, R. Ph., Inspector Michael Kidd, R. Ph., Inspector Frank Van Fleet, R. Ph., Inspector Barbara A. Wood, R. Ph. Inspector Sidney "Sid" Werges, R. Ph., Inspector

EXECUTIVE DIRECTOR

Kevin E. Kinkade, R.Ph.

#### **OFFICE STAFF**

Sharon Roberts

Tammy Siebert

Regina Divine

Don Walker

Nancy Gillam

Julie Peters

Sheila Ivory

Executive Assistant

Compliance Coordinator

Pharmacist Coordinator

Drug Distributor Coordinator

Licensing Technician I

Pharmacy Coordinator

Pharmacy Technician Coordinator

#### **DIVISION OF PROFESSIONAL REGISTRATION**

# ORGANIZATION AND DESCRIPTION OF THE BOARD OF PHARMACY

The Missouri Board of Pharmacy is an agency within the Division of Professional Registration, Department of Economic Development. The Board's mission is to promote, preserve and protect the public health, safety and welfare by assuring the provision of quality pharmaceutical care to the citizens of Missouri, through the regulation of the practice of pharmacy.

The Board was created by House Bill No. 87 of the General Assembly of 1909. The Board consists of seven (7) persons, one who is a public member and six (6) who are licensed pharmacists actively engaged in the practice of pharmacy. At least one of these members must be a person who provides, on a full-time basis, pharmaceutical services to a hospital, skilled nursing facility or an intermediate care facility. Board Members are appointed by the Governor and hold office for (5) years from the date of their appointment and until their successors have been appointed and qualified. Board Members appointed by the Governor are subject to approval of the Senate. Annually, the Board shall organize by the election of a president, and a vice president, each of whom serves for one year.

The Board is provided authority by Section 338.035, 338.140, 338.280 and 338.350 RSMo. 2000 to adopt rules and regulations for the application and enforcement of Chapter 338, RSMo.

The Board has superintending control over the practice of pharmacy in the State of Missouri and its primary duties consist of:

- 1. Examining and licensing of applicants;
- 2. Accrediting of pharmacy colleges;
- 3. Renewing biennially, the licenses of qualified pharmacists, pharmacies, drug distributors, and renewing annually, the licenses of intern pharmacists;
- 4. Investigation of complaints involving any licensee or registrant received including public complaints, information from other state and/or federal agencies, or violations discovered during routine inspections of pharmacy and drug distributor operations;
- 5. Suspending, revoking, or placing on probation the license of any pharmacist, pharmacy, drug distributor, or intern pharmacist found to be in violation of Chapter 338, RSMo;
- 6. Inspection of pharmacies and drug distributors;
- 7. Inspection and licensing of pharmacies for intern certification;
- 8. Licensing and biennial renewal of non-resident pharmacies and drug distributors;
- 9. Registering and renewing pharmacy technicians annually.

The Board maintains a record of all of its proceedings through the maintenance of minutes for both its open and closed session meetings, pursuant to provisions in Chapter 610 and 620.

The Board appoints five members to an Advisory Committee for Drug Distributors. This committee advises and makes recommendations to the Board concerning any rule changes proposed involving the drug distributor licensing program. A list of the current members of the committee is available at the Board of Pharmacy office.

Several publications are available through the Board of Pharmacy. These include the Annual Report, the Board of Pharmacy Red Lawbook, the Consumers Report and the Board of Pharmacy quarterly Newsletter.

The Board is an active member of the National Association of Boards of Pharmacy, and a member of District 6 in NABP.

KEVIN E. KINKADE, R.PH EXECUTIVE DIRECTOR

#### **BOARD STRATEGIC PLAN**

At an annual Retreat in March, the board identifies both current and expected pharmacy issues, reviews statutes and regulations, and develops a strategic plan for the next year. They also review board office activities, review statistics and identify areas, which need improvement or change. The Strategic Plan is then a part of the April regular board meeting agenda for approval or revision. Once the Strategic Plan is approved, the Executive Director initiates the necessary action within the Board Office and with field staff, to meet the goals established. As activity occurs, the plan is updated and is a part of each board meeting open agenda. Issues identified and added to the Strategic Plan for 2003-2004 are:

- ♦ Review of present standards governing internship
- ♦ Promote legislative changes which will enhance Board's ability to provide proper oversight of the profession resulting in positive outcomes for public health
- ♦ Establish an e-mail network between Board and pharmacies/drug distributors.
- **♦** Improve the flow of information to complainants from board office concerning outcome of investigations.
- ♦ Update regulations in order to provide up-to-date minimum standards to promote public health
- Work with the Board of Healing Arts to provide a joint policy statement, which will form the basis for practice and enforcement standards for Internet prescribing and dispensing.

#### **\$\$ FINANCIAL INFORMATION \$\$**

The Missouri Board of Pharmacy's appropriation for fiscal year ending June 30, 2003 was as follows:

Personal Service \$545,727 Expense and Equipment \$327,664

Criminal History Fund \$ 41,140 E Transfers\* \$ 474,725

\*Transfers include:

- Rent
- Professional Registration
- Optical Imaging
- DED/MIS
- Hancock Refunds
- Licensing System
- Attorney General
- Administrative Hearing Commission
- Office of Administration Allocated Expenses

#### **BOARD MEETING INFORMATION**

During the fiscal year ending June 30, 2003, the Board met in regular session a total of 10 days.

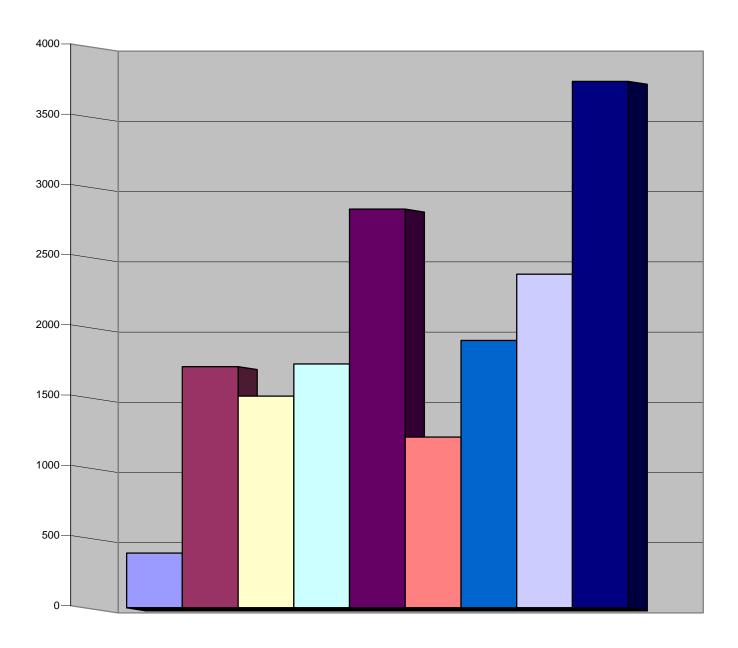
#### INSPECTION INFORMATION

During the fiscal year ending June 30, 2003, the seven (7) board inspectors conducted a total of 998 regular inspections of pharmacies and drug distributors throughout the state. This total does not include additional trips to a pharmacy or drug distributor for follow-up inspections or investigations.

#### **GOLD CERTIFICATES ISSUED**

The following individuals received Gold Certificates during FY 2003, which are signed by the Governor of the State of Missouri, as well as by the Board Members and the Executive Director. The certificate represents fifty (50) years of active service as a Missouri Pharmacist.

Adams, Robert E	Lebanon		MO
Balk, Blair G	Clayton		MO
Barks, R D	Florissant		MO
Bena, Richard A	<b>Des Peres</b>		MO
Benteman, Norman R	Concordia		MO
Bergman, Kenneth H	<b>Lees Summit</b>		MO
Bisceglia, Francis P	Kansas City		MO
Branum, Maurice J	Joplin		MO
Cooper, Eugene L	Surprise		$\mathbf{AZ}$
Coran, Aubert	Longboat Key	$\mathbf{FL}$	
Dempsey, Kenneth J	Sikeston		MO
Goldberg, Sidney A	Olivette		MO
Greene, Everett F	Kansas City		MO
Heller, Donna J	Saint Louis		MO
Jackson, John E, Jr	St Louis		MO
Juengel, William A	St Clair		MO
Klotz, Raymond F	Kirkwood		MO
Mohan, Thomas J, Jr	Laplata		MO
Newman, Melvin K	St. Louis		MO
Oris, William C	Florissant		MO
Rosenhauer, Edward C	St Louis		MO
Shmuger, Samuel S	St Louis		MO
Stephens, E Eugene	Columbia		MO
Stoll, Don H	Columbia		MO
Thorn, Denzil L	Chapel Hill		NC
Walker, William D	Licking		MO
Weinstein, Ernest H	Kansas City		MO
Wolter, David H	St Charles		MO
Zike, Golden D, Jr E	Alton		$\mathbf{IL}$





#### OTHER BOARD INFORMATION

During the calendar year 2003, the seven (7) employees of the Board of Pharmacy received and responded to 21,509 incoming telephone calls, covering a variety of subjects. The major topics are indicated in the chart shown above. This number represents an increase of over 2,300 calls for the same period a year prior.

#### **BOARD RULES FILED OR AMENDED**

- **4 CSR 220-2.010 Pharmacy Standards of Operation -** Added Class J language re PIC on duty definition and allows hospice/home health nurses to possess alteplase (9/02 amendment incorporated into other amendment) (9) deleted 12/02. **Effective 9/30/03.**
- **4 CSR 220-2.030 Educational and Licensing Requirements -** Deleted (6)(K) which conflicts with (6)(I) re time a reciprocity application is valid. **Effective 6/30/03.**
- 4 CSR 220-2.190 Patient Counseling Added DUR provisions. Effective 6/30/03.
- **4 CSR 220-2.700 Pharmacy Technician Registration -** Added language re additional conditions/restrictions if technician violates existing conditions/restrictions. **Effective 6/30/03.**
- 4 CSR 220-2.200 Sterile Pharmaceuticals Rescission and new rule. Effective 6/30/04.
- 4 CSR 220-2.400 Compounding Standards of Practice Revision of rule. Effective 7/31/03.
- **4 CSR 220-2.020** (h) **Pharmacy Permits -** Changed reference to sterile pharmaceutical rule. **Effective 6/30/03.**
- 4 CSR 220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy Deleted (2) since it referred to Sterile Pharmaceutical rule. Effective 6/30/03.
- 4 CSR 220-2.900 Automated Dispensing and Storage Systems Many amendments. Effective 9/30/03.
- **4 CSR 220-2.130 Drug Repackaging -** Changed language re labeling in automated dispensing systems. **Effective 8/31/03.**
- 4 CSR 220-5.020 Drug Distributor Licensing Requirements Redefined wholesale drug distributor, concerning unlicensed activity; required fax #s. Effective 1/30/04.

# DISCIPLINARY INFORMATION COMPLAINTS FILED

## STATISTICS BELOW REFLECT TOTAL COMPLAINTS FOR THE FISCAL YEAR ENDING JUNE 30, 2003

Total Complaints Received and Reviewed by the Board .......404

TYPES OF COMPLAINTS INVOLVED		
Adulterated Drugs	7	
Alcohol	4	
Compounding	13	
Confidentiality	3	
Counseling	1	
Disciplinary Action in Another State	8	
Discipline Revisions	5	
Dispensing Errors	55	
Drug/Alcohol Related	4	
Drug Distributor Violations	6	
Ethical	2	
Expired Drugs	2	
Felony Conviction	9	
Fraud-Unspecified	5	
Fraudulent Prescriptions	3	
Improper Controls	23	
Improper Dispensing	41	
Incompetence	1	
Licensure applicant	44	
Loss of Drugs	18	
Misbranding	1	
Mislabeling	4	
No Jurisdiction	23	
Pharmacy Permit Violations	18	
Practicing without a License	38	
Recordkeeping	8	
Sale of Drugs for illegal purposes	1	
Samples	1	
Security	3	
Substitution	4	
Theft of Drugs	23	
Theft of Drugs for Self-Administration	4	
Theft of Drugs for Sale to others	1	
Theft of Money	2	
Unauthorized Dispensing	12	
Unauthorized Refills	3	
Unsanitary Pharmacy	1	
Unsupervised Dispensing	1	
Violation of Disciplinary Order	2	

#### SOURCE OF COMPLAINTS

Complaints Received From Public	177
Complaints Received from Other Agencies	5
Complaints Received from Board Inspectors	71
Complaints Received from Other State Boards	3
Complaints Regarding Licensing Issues	148

#### **DISPOSITION**

Administrative Correction Letters Sent	39
Administrative Warning Letters Sent	36
Professional Misconduct Letters Sent	11
Cease and Desist Letters Sent	14
Denial Letters Sent	4
Technician Disqualification Letters Sent	46
Miscellaneous Non-Administrative Board Letters Sent	5
Complaints Referred to Attorney General's Office	57
Investigations Requested/Not Complete	95
Individuals Requested to Meet with the Board	30
No Action/Insufficient Evidence	70
Disposition Complete – Other	62

#### NOTE

Disposition numbers will not equal the number of complaints received and processed, since some cases resulted in dual action, i.e., the pharmacist met with the Board and then received some type of letter, or was referred to the Attorney General's office for filing, etc.

#### **DISCIPLINE**

#### **ACTIONS**

Complaints Filed with Administrative Hearing Commission	4
Disciplinary Hearings Held	3
Felony Hearings Held	0
Settlement Agreements Entered	16
Settlement Agreements w/AHC	2
Restricted Licenses Issued Pursuant to Section 620.149	4
Violation Hearings Held	7

#### **DISCIPLINE RESULTS**

Pharmacy Permit Denials	3
Pharmacist Licenses Revoked	8
Pharmacist Licenses Suspended Followed by Probation	5
Pharmacist Licenses on Probation	16
Pharmacist Licenses Censured	1
	1
Pharmacy Permits on Probation	4
Pharmacy Permits Suspended Followed by Probation	1
Drug Distributor License Denials	1
Drug Distributor Licenses on Probation	1
Injunction	1
Restricted Pharmacist Licenses Issued Pursuant to Section 620.149	2
Restricted Pharmacy Permits Issued Pursuant to Section 620.149	2

#### NOTE

Since the time frame of cases from point of first review to the final disposition may be lengthy, the totals shown above will not necessarily balance. A case may be reviewed by Board, referred to the Attorney General's office, filed with the Administrative Hearing Commission and be decided by disciplinary hearing, consent order or otherwise, all in separate fiscal years.

#### CENSUS OF LICENSED PHARMACISTS YEAR ENDING JUNE 30, 2003









#### TOTAL PHARMACISTS INSTATE AND OUT OF STATE

<b>Total Licensed Pharmacists</b>	7,123
Active license	6,825
Male	3,857
Female	2,968
Inactive license	298
Male	173
Female	125

#### TOTAL NUMBER OF PHARMACISTS RESIDING IN MISSOURI

Active License – Practicing Pharmacy	4,589
Male	2,673
Female	1,916
Inactive License – Not Practicing Pharmacy	68
Male	46
Female	22

#### BREAKDOWN OF EMPLOYMENT STATUS IN MISSOURI

Retail Pharmacy (Independent)	1,238
Community Pharmacy (Chains)	2,170
Hospitals and Clinics	1,651
Nursing Homes	155
Consulting	118
Nuclear	40
Home Health	82
Teaching	106
Retired	165
Not Practicing in Missouri	133
Not Active in Pharmacy	386
Unemployed	129
Manufacturing	61
Government	49
Armed Services	5
Sterile Products	22
Other	133
Unknown	420

#### AGE GROUP BREAKDOWN OF INSTATE AND OUT-OF-STATE PHARMACISTS

Under the age of 30	763
Ages 30-39	1,765
Ages 40-49	2,002
Ages 50-59	1,586
Ages 60-69	669
Ages 70-79	294
Ages 80-89	40
Ages 90+	3









#### CENSUS OF LICENSED PHARMACIES AS OF JUNE 30, 2003

Total Licensed Pharmacies As Of June 30, 2003	
Instate Pharmacies	
Non-Resident Pharmacies	290



#### **BREAKDOWN OF INSTATE PHARMACIES**

Class A-Retail Pharmacies (Independent)	224
Class A - Chain Pharmacies	473
Class B - Hospital Pharmacies	115
Class C - LTC Pharmacies	15
Class D – Home Health Pharmacies	4
Class E – Radiopharmaceutical	8
Class F – Renal Dialysis Pharmacies	2
Class G – Medical Gas Pharmacies	1
Class H – Sterile Products	1
Class I – Consultant Pharmacy	1
Class J – Shared Services Pharmacy	1
Pharmacies With Multiple Classes	405

#### CENSUS OF DRUG DISTRIBUTORS/MANUFACTURERS LICENSED AS OF JUNE 30, 2003

Total Drug Distributors Licensed with a Permanent License	955
Total Drug Distributors Licensed with a Temporary License	51
Total Out-of-State Manufacturers Registered	32



#### **NOTE**

Any out-of-state drug company or manufacturer that ships/transfers legend drugs or devices into this state is required to obtain an out-of-state drug distributor license with this office.

Upon receipt of a license application, the company is issued a temporary license. This temporary license is valid for a period of one (1) year or until the application has been completely processed by this office, at which time, a permanent license is issued or the application is denied by the Board.

All in-state drug companies that ship/transfer legend pharmaceuticals are also required to obtain licensure with this office.

Any pharmacy that distributes legend drugs to any entity other than the consumer (the patient), such as other pharmacies, physicians, etc., must obtain a drug distributor's license if that type of distribution exceeds 5% of the pharmacy's total gross sales.

#### **CENSUS OF OTHER LICENSEES AS OF JUNE 30, 2003**

Total Licensed Interns	471
Total Registered Pharmacy Technicians	9.126